2020

# Genetic Engineering, Lack of Regulation in the United States of America and its Potentially Problematic Applications

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## Introduction

Humans have been manipulating genes for thousands of years[1], examples include domesticating wild wolves into family-friendly companions[2] or the cultivation of wild apples into their present-day larger and sweeter form[3]. In the last half century humans went from simply influencing and modifying genes through selective breeding[4] and other means to having the ability to alter genetic material in a laboratory using genetic engineering technology[5]. The altering of genes of agricultural products is perhaps the more commonly known form of genetic engineering[6]. We have genetically altered lettuce with scorpion venom to reduce the need for pesticides[7] and altered the photosynthesis in rice to produce higher yields[8]. Another commonly known form is in vitro fertilization[9], which led to the first technologically assisted reproduced baby in 1978[10]. Other than these commonly known genetic engineering technologies, there are yet even more available to the scientific research community, like Zinc-Finger Nucleases, TALENs and CRISPR-Cas9[11].

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[1] STEVE PARKER, GENETIC ENGINEERING 16 (CHICAGO, ILL: RAINTREE 2005).
[2] SCOTT J.P, EVOLUTION AND DOMESTICATION OF THE DOG, EVOLUTIONARY BIOLOGY (SPRINGER, BOSTON, MA 1968).
[3] Amandine Cornille, et al., *The domestication and evolutionary ecology of apples,* Trends in Genetics (2014).
[4] PARKER, supra note 1.
[5] JEFFREY H. MILLER ET AL., ENCYCLOPEDIA OF GENETICS (SAN DIEGO: ACADEMIC PRESS, 2002).
[6] Rajul K. Gupta et al., *Food safety in the 21st century: Public Health Perspective*. (London: Academic Press, 2017).
[7] Sheng Jian Jiet al., *Recombinant Scorpion Insectotoxin Aait Kills Specifically Insect Cells but Not Human Cells*, 12 The National Laboratory of Protein Engineering and Plant Genetic Engineering 143 (2002).
[8] PL Mitchell et al., *Redesigning Rice Photosynthesis to Increase Yield*, The Quest to Reduce Hunger (2000).
[9] ILPO HUHTANIEMI, ENCYCLOPEDIA OF ENDOCRINE DISEASES 595-598 (OXFORD: ACADEMIC PRESS, 2D ED. 2019).
[10] Joseph Schulman et al., *A Personal Viewpoint*, Charleston, SC: Joseph D. Schulman (2010).
[11] U.S. FED. DRUG ADMIN., THERAPEUTIC CLONING AND GENOME MODIFICATION (2018), https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm2007205.htm

To sum up, genetic engineering technology has allowed us to observe, understand and even rewire the DNA of organisms[12]. Today, there is a boom in development in this area of science, thanks to a newly applied system called CRISPR-Cas9[13]. CRISPR-Cas9 is fairly new genetic engineering technology that has been at the center of various scandalous events within the science community. In 2017, Josiah Zayner[14], a self-proclaimed "bio-hacker" live-streamed himself on social media injecting himself with un-tested, non-FDA approved muscle-growth gene therapy created with the use of CRISPR-Cas9[15]. His action was followed by two more "bio-hackers" from the Ascendance Biomedical[16] company, who also injected themselves with an experimental HIV gene-therapy[17] and an experimental herpes treatment[18,19]. Today, Zayner sells "do-it-yourself" CRISPR kits through his website[20]. The United States Federal Drug Administration[21] (FDA) issued a statement[22] in 2017 stating that the sale of products intended for self-administration such as the do-it-yourself kits made to produce gene therapies were against the law.

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[12] Desmond S. Nicholl, *An introduction to genetic engineering*, Cambridge New York: Cambridge University Press, (2008)
[13] Tahere Seifi, *Introduction Of CRISPR/Cas System, As a Genetic Interference Pathway and Essential Factor in Genome Evolution*, Health Biotechnology and Biopharma (2017).
[14] THE ODIN, http://www.the-odin.com/about-us/ (last visited on December16, 2018).
[15] A Biohacker Regrets Publicly Injecting Himself With CRISPR, THEATLANTIC.COM, https://www.theatlantic.com/science/archive/2018/02/biohacking-stunts-crispr/553511/ (last visited on December16, 2018).
[16] Ascendance Biomedical, https://www.linkedin.com/company/ascendance-biomedical/about/ (last visited on December16, 2018).
[17] Emily Mullin, *Before He Died, This Biohacker Was Planning A CRISPR Trial In Mexico*, THE MIT TECHNOLOGY REVIEW, May 4, 2018, https://www.technologyreview.com/s/611076/before-he-died-this-biohacker-was-planning-a-crispr-trial-in-mexico/.
[18] Emily Mullin, *A Biotech CEO Explains Why He Injected Himself With A DIY Herpes Treatment On Facebook Live*, THE MIT TECHNOLOGY REVIEW, February 5, 2018, https://www.technologyreview.com/s/610179/a-biotech-ceo-explains-why-he-injected-himself-with-a-diy-herpes-treatment-live-on-stage/.
[19] None of the three experimental injections produced any results.
[20] THE ODIN, The-ODIN.com (last visited on December16, 2018).
[21] THE FDA, https://www.fda.gov/ (last visited on December16, 2018).
[22] Information About Self-Administration of Gene Therapy, November 21, 2017, https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm586343.htm.

Enter, the CRISPR baby scandal[23]. News broke on November 25, 2018[24] by MIT Technology Review that He Jiankui[25], a young Chinese scientist and his research team at the Southern University of Science and Technology[26], in Shenzhen, China created the world's first genetically-engineered babies, the application with the Chinese Clinical Trial Registry[27] and other documentation which can be viewed online[28,29]. He and his team recruited six couples, each set being an HIV-negative mother and HIV-positive father. The team used CRISPR-Cas9 to disable the CCR5 gene in fertilized eggs to produce HIV-resistant babies. The CCR5 gene, also known to act as a doorway that allows HIV to enter the white blood cells, infects the carrier with HIV if exposed. The team then implanted these modified embryos in all the women. Only one pregnancy was brought to full term. The result was the birth of a set of twins, Lulu and Nana, the world's first genetically-engineered "HIV-resistant children," according to He. Additionally, a United States professor of physics and bioengineering at Rice University, Michael Deem, is being investigated for his involvement in the research and the experiment[30]. To date, He's work has not been published in any scientific journals and none of his work has been independently verified. Credible verification would require independent peer-review of He's work and comprehensive DNA sequencing of both parents and the twins[31].

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[23] Chris Zielinski, T*he CRISPR Baby Scandal Gets Worse by the Day*, HEALTH INFORMATION FOR ALL, DECEMBER, 6, 2018, https://www.hifa.org/dgroups-rss/crispr-baby-scandal-gets-worse-day.
[24] Antonio Regalado, *EXCLUSIVE: Chinese scientists are creating CRISPR babies*, MIT TECHNOLOGY REVIEW, November 25, 2018, https://www.technologyreview.com/s/612458/exclusive-chinese-scientists-are-creating-crispr-babies/.
[25] https://www.linkedin.com/in/jiankui-he-a1917517/.
[26] Southern University of Science and Technology, http://sustc.edu.cn/en/
[27] China's Clinical Trial Registry, http://www.chictr.org.cn.
[28] http://www.chictr.org.cn/showprojen.aspx?proj=32758
[29] http://www.chictr.org.cn/uploads/file/201811/bb9c5996d8fd476eacb4aeecf5fd2a01.pdf
[30] Greg Toppo, *Did Rice Scholar Assist in Banned Research?*, INSIDE HIGHER ED.COM, https://www.insidehighered.com/news/2018/11/27/rice-investigate-scholar-gene-editing-case.
[31] Tina Hesman, *Chinese Scientists Raise Ethical Questions With First Gene-Edited Babies*, SCIENCE NEWS, https://www.sciencenews.org/article/chinese-scientists-raise-ethical-questions-first-crispr-gene-edited-babies.

Part I will explain in more depth what CRISPR-Cas9 is and how it works; as well as why non-regulation or deficient regulation is a human rights issue. Next, Part II identifies the current regulatory framework for gene-editing internationally, focusing on the position of the United Nations, comparing that to China and finally The United States of America.

Lastly, Part III seeks to identify potential applications and consequences if the United States were to adopt the generally accepted regulatory framework as the United Nations or their peer countries. I ultimately conclude that a global consensus needs to be reached in order to safeguard human rights, this requires regulation of not only germline cell editing but also somatic cell editing, as I have also identified one of many potentially problematic applications.

**Part I: A Short History of CRISPR-Cas9**

CRISPR-Cas9 is a two-part system. CRISPR pronounced "crisper," stands for "clusters of regularly interspaced short palindromic repeats, and is a naturally-occurring mechanism in prokaryotes[32] such as bacteria[33] and archaea[34]. Bacteria and archaea[35] cells naturally have an adaptive immune system called CRISPR that allows them to detect viral DNA and destroy it[36].

Cas-9 is a protein that acts like a pair of molecular scissors[37]. In 2012, a team led by Jennifer Doudna[38], a professor in the Department of Chemistry and Chemical Engineering and

[32] A prokaryote is "a simple, single-celled organism that lacks a nucleus and membrane-bound organelles." https://www.khanacademy.org/science/high-school-biology/hs-cells/hs-prokaryotes-and-eukaryotes/a/prokaryotic-cells.
[33] F.A. Ran, *Genome Engineering Using The CRISPR-Cas9 System*, Nature Protocols, 2281–2308 (Vol. 8, 2013).
[34] Rodolphe Barrangou, *The Roles Of CRISPR–Cas Systems in Adaptive Immunity and Beyond*, Current Opinion in Immunology 36-41 (Vol. 32, 2015).
[35] *Bacteria And Archaea is a Single-Celled Microorganisms*, https://basicbiology.net/micro/microorganisms/archaea (last accessed December 16, 2018).
[36] Barrangou, supra note 55.
[37] Mahmood Khan et al., *CRISPR/Cas9: The Jedi Against the Dark Empire Of Diseases.*, J Biomed Sci. (2018)
[38] https://www.hhmi.org/scientists/jennifer-doudna

the Department of Molecular and Cell Biology[39] at the University of California, Berkeley and Emmanuelle Charpentier[40], director at the Max Planck Institute for Infection Biology[41] in Berlin, Germany proposed harnessing the function of the system as a genetic engineering technology[42]. That same year, Feng Zhang[43], a core institute member of the Broad Institute of MIT and Harvard[44] and his team were able to use CRISPR-Cas9 to cut human DNA in specified places[45]. These discoveries launched a years-long patent dispute between the University of California, Berkeley and the Harvard and MIT-affiliated institute, eventually leading the United States Court of Appeals for the Federal Circuit to affirm a lower court's finding that the Broad Institute holds the patent rights to CRISPR-Cas9[46] in September 2018.

The CRISPR-Cas9 system (hereinafter CRISPR for short) is unique in that, not only is it cheaper[47] than other genetic engineering technologies, but in comparison, is easier to use and is more precise[48]. According to the University of California, Berkeley, anyone can make tens of thousands of precisely guided probes covering an organism's entire genome for less than $100 in supplies[49]. These developments lend themselves to widespread accessibility, it's use is no longer limited to a lab, schoolchildren are using it in their classrooms[50] and you can even buy a DIY kit

[39] University of California, Berkeley, https://chemistry.berkeley.edu/faculty/chem/doudna (last accessed December 16, 2018).
[40] https://www.emmanuelle-charpentier-lab.org/
[41] https://www.mpiib-berlin.mpg.de/2285/en
[42] Jennifer A. Doudna et al., *A Programmable Dual-RNA–Guided DNA Endonuclease in Adaptive Bacterial Immunity*, 337 Science, 816-821 (2012).
[43] https://zlab.bio/
[44] Broad Institute, https://www.broadinstitute.org/bios/feng-zhang (last accessed December 16, 2018).
[45] https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline
[46] Regents of the Univ. of Cal. v. Broad Inst., Inc., 903 F.3d 1286 (Fed. Cir. 2018).
[47] Robert Sanders, *Simple Technology Makes CRISPR Gene Editing Cheaper*, BERKELEY NEWS, https://news.berkeley.edu/2015/07/23/simple-technology-makes-crispr-gene-editing-cheaper/
[48] Id Sanders.
[49] Id Sanders.
[50] Alan Yu, H*ow A Gene Editing Tool Went From Labs To A Middle-School Classroom*, NPR NEWS, https://www.npr.org/sections/alltechconsidered/2017/05/27/530210657/how-a-gene-editing-tool-went-from-labs-to-a-middle-school-classroom.

online for $150[51]. These key features make CRISPR the most popular system on the market[52]. It has become so popular that it has been dubbed "the rock star tool of biology[53]" by the American Association for the Advancement of Science, even boasting an annual fan convention called CRISPRcon[54]. In 2015 CRISPR was named *Science'*s Breakthrough of the Year[55]. Despite its popularity, many scientists remain wary of ethical dilemmas and practical dangers, even by Jennifer Doudna, one of its own co-inventors. Doudna described in her book, A Crack in Creation: The New Power to Control Evolution, that the early years after publishing her work, she had a reoccurring a nightmare of Hitler coming up to her with pig-like features wanting to learn about CRISPR[56]. Dawn Sinclair Shapira, filmmaker of "The State of Eugenics," says, "in the wrong hands could become a tool of oppression[57]." There are two major debates[58]: (a) germline editing versus somatic editing and (b) therapy versus enhancement. I will discuss these in turn.

## 1) The Two Major Debates

### a) Germline Editing Versus Somatic Editing

There are two ways to edit human genes: germline editing and somatic editing[59]. Somatic editing[60] involves making a genetic edit of a non-reproductive cell of a fully developed

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[51] http://www.the-odin.com/diy-crispr-kit/
[52] Alice Park, The Crispr Pioneers, TIME MAGAZINE, http://time.com/time-person-of-the-year-2016-crispr-runner-up/.
[53] Jon Cohen, *CRISPR is Too Fat for Many Therapies, So Scientists are Putting the Genome Editor on a Diet*, SCIENCE MAG, https://www.sciencemag.org/news/2018/08/crispr-too-fat-many-therapies-so-scientists-are-putting-genome-editor-diet.
[54] https://crisprcon.org/
[55] John Travis, *Making the Cut*, SCIENCE MAG, http://science.sciencemag.org/content/sci/350/6267/1456.full.pdf.
[56] Jennifer Doudna et al., A CRACK IN CREATION: THE NEW POWER TO CONTROL EVOLUTION (2017)
[57] Damian Garde, *What we heard at CRISPRCon: talk of designer babies, IP battles, and scientific colonialism*, STAT NEWS, https://www.statnews.com/2018/06/05/crisprcon-boston-crispr-gene-editing/.
[58] "Designer DNA," Explained, season 1, episode 16. Netflix
[59] A.J.F. Griffiths et al., *Somatic versus germinal mutation*, AN INTRODUCTION TO GENETIC ANALYSIS (New York: W. H. Freeman, 7th ed. 2000) (https://www.ncbi.nlm.nih.gov/books/NBK21894/).
[60] "Somatic cell gene therapy involves the placement of a human gene into a living person's somatic cells—cells that do not produce the eggs and sperm that in turn produce the next generation. Somatic cell gene therapy would aim to

individual organism. This type of edit stays with the organism, meaning it would not be passed on genetically. An example is when CRISPR was used on four dogs, they successfully reversed muscular dystrophy on all the dogs at the University of Texas Southwestern Medical Center,[61] however the progeny of these dogs would not be genetically resistant to developing muscular dystrophy. Another example is when it was used to create mice that were resistant to cocaine-seeking behavior and even immune to cocaine overdose[62].

Germline editing involves editing the human germ cell or embryo[63]. Editing at the germline or embryonic level means that the edit would be passed down genetically to its progeny[64], in contra to the natural progression of human evolution[65]. An example is when CRISPR was used to correct a potentially fatal genetic disorder in 16 out of 18 non-viable embryos at the ShanghaiTech University in China[66]. Had the embryos in the Chinese study been viable, implanted and carried to term, the end-result would be a modified human who would carry on the "edit" to future generations. Currently the only known germline edit on a viable human embryo that lead to the creation of the world's first genome-edited children was done in China in 2018. This hotly contested act was perpetrated by He Jiankui, who claims he and his team created "HIV-resistant" twins, their names Lulu and Nana[67]. He has also claimed a second

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cure a disease only in the patient, not in the patient's descendants." H.T. Greely, *Ethical Issues in the 'New' Genetics*, 4762-4770, International Encyclopedia of the Social & Behavioral Sciences (2001)

[61] Megan Molteni, *CRISPR HALTED MUSCULAR DYSTROPHY IN DOGS. ARE HUMANS NEXT?*, Wired, https://www.wired.com/story/crispr-halted-muscular-dystrophy-in-dogs-someday-it-might-cure-humans/.

[62] Yuanyuan Li et al., Genome-edited skin epidermal stem cells protect mice from cocaine-seeking behaviour and cocaine overdose, NATURE BIOMEDICAL ENGINEERING (2018).

[63] Kelly Ormond et al., *Human Germline Genome Editing*, 101, AJHG, 167 (2017).

[64] Tetsuya Ishii, *Reproductive medicine involving genome editing: clinical uncertainties and embryological needs*, 34 REPRODUCTIVE BIOMEDICINE, Online, 27 (2017).

[65] James J.Bull et al., *Arresting Evolution*, 33 TRENDS IN GENETICS, 910 (2017).

[66] Kristin Houser, *A NEW CRISPR TECHNIQUE LET RESEARCHERS REPAIR A GENETIC MUTATION IN VIABLE HUMAN EMBRYOS*, FUTURISM, https://futurism.com/base-editing-crispr-marfan/.

[67] He Jiankui, *About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos*, https://www.youtube.com/watch?v=th0vnOmFltc

pregnancy with a gene-edited embryo is in its early stages[68]. More on this in Part II, section b, The People's Republic of China below.

The difference between these two kinds of editing, whether the modified gene is passed down genetically to future generations or not is simple, but has devastating consequences. We do not have a full understanding of germline cells, of what sweeping implications modification or elimination of a gene may have, and what effect diminished genetic diversity would have on the human race and our entire ecosystem. Please see a more in-depth discussion of this topic in the section on ethical concerns below.

**b) Therapy Versus Enhancement**

Therapeutic editing and enhancement editing is another equally contested major debate[69]. Genetic editing that is considered "therapeutic" treats or prevents diseases, disabilities or impairments[70]. Enhancement editing involves creating improvements like augmenting intelligence or enhancing athletic performance[71]. It is the expression of preferred traits as to "superficial" features like skin color or eye color[72]. While differentiation in this kind of editing seems obvious, many scientists are concerned about where the lines will be drawn as to which ailments should be labeled "medical" in order to be considered a therapeutic edit, and not an enhancement[73]. And once that determination is made, will it create negligence in the parents who have not "genetically-corrected" their children? Those with genetic modifications would be a

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[68] Megan Molteni, *ROGUE SCIENTIST SAYS ANOTHER CRISPR PREGNANCY IS UNDERWAY*, WIRED, https://www.wired.com/story/he-jiankui-gene-editing-crispr-second-pregnancy/
[69] "Designer DNA," Explained, season 1, episode 16. Netflix.
[70] Therapy vs. Enhancement, THE CENTER FOR BIOETHICS, http://www.cbc-network.org/issues/faking-life/therapy-vs-enhancement/.
[71] E. Rodriguez, *Ethical Issues in Genome Editing using Crispr/Cas9 System*. J. CLIN. RES. BIOETH. (2016).
[72] O.P .Perera, *CRISPR/Cas9 mediated high efficiency knockout of the eye color gene Vermillion in Helicoverpa zea*, BODDIE, (2018).
[73] Heidi C. Howard, *One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans*, 26 EUROPEAN JOURNAL OF HUMAN GENETICS 1, 1–11 (2018).

"privileged elite," as Heather Long, a journalist for The Washington Post, calls them, a group of humans who will have obvious intergenerational advantages over others and "further exacerbate our world of haves and have nots."[74]

**c) The Ethical Concerns**

The ethical concerns would probably be best understood under bioethical standards. Central to the practice of medicine and biological sciences are "The Four Principles of Bioethics,[75]" also known as the four-principles approach.[76] This approach was developed by two American philosophers, Tom Beauchamp[77] and James Childress.[78] This approach has long held that at the root of biomedical ethics are the following four principles: respect for autonomy, beneficence, non-maleficence and justice. These principles will lay the fundamental groundwork for each foreseeable potential human rights violation I state below.

Personal autonomy means the right to make his or her own choice[79]. This principle will be violated if germline editing is allowed, mainly because it affects future generations as discussed above, given their obvious lack of consent as to inherited modified genes. The creation of a heritable modified genes has unpredictable implications on humankind and evolution[80]. In a 2018 commentary article authored by professors and research scholars noted there may be unintended consequences to editing out harmful mutations in humans:

> Here we simply emphasize to express that it may have effect modification of mutations in germ cell will ultimately eliminate that mutation in the next generation, which will deter the on-going human evolution. Mutations are an essential part of evolution, whose pros and cons cannot be judged instantly. The mutations, which seem deleterious today, may have inclusive fitness

[74] Heather Long, *Selecting a Child's Genetic Traits*, OPPOSING VIEWPOINTS SERIES: HUMAN GENETICS (2014)
[75] T.l. Beauchamp et al., PRINCIPLES OF BIOMEDICAL ETHICS. (Oxford: Oxford University Press, 5th ed. 2001).
[76] https://depts.washington.edu/bioethx/tools/princpl.html
[77] https://kennedyinstitute.georgetown.edu/people/tom-beauchamp
[78] https://bioethics.virginia.edu/faculty/profile/jdfc7c
[79] http://www.jblearning.com/samples/0763760633/60632_CH02.pdf
[80] K. Krishan, *Germline Editing: Editors Cautionary* (2018)

> tomorrow. Mutations, which seem harmful today, may be the nature's preparation for tomorrow. The somatic cell modifications in humans whereas provide answer to many ailments, the germ line changes until outcomes of such modifications are uncontrolled would continue to raise ethical concerns. Thus, the researchers need to be doubly cautious and some stringent regulations should be framed regarding the various aspects of germ line gene modifications and any potential conflict with nature for future outcome.[81]

Moreover, the elimination of a gene or modification of a gene could affect the genetic diversity of the human population[82]. The United Nations has defined genetic diversity as, "[t]he variation in the amount of genetic information within and among individuals of a population, a species, an assemblage, or a community."[83] Genetic diversity is our inherited toolkit, and the more varied the genes are in our toolkit as a population, the higher our survivability will and continue to be. "Genetic diversity has a direct relation to the fitness and survivability of various species and populations; as genetic diversity decreases within a population, so does the fitness and survivability of that population."[84] Notably, we do not understand the far-reaching potential of a gene, whether it is consider a harmful mutation today or not, it may serve a purpose tomorrow. Employing such a germline edit that would be inherited by future generations without their consent. The lack of medical consent of future generations is a contravention of human rights as it breaches their physical integrity, their ability to make choices as to their own bodies. Foreseeable issues as to consent have been posed by several scientists. Per legal standards and clinical ethics, it's long been established that parents are the best and most appropriate decision-makers over their children until they have reach adulthood. But this presumption is not perfect as

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[81] Id. Krishan
[82] Christian Wolfe, *Human Genetic Diversity and the Threat to the Survivability of Human Populations*, Washington & Jefferson College, https://www.ohio.edu/ethics/2003-conferences/human-genetic-diversity-and-the-threat-to-the-survivability-of-human-populations/.
[83] UN (1992) Environment and Development (Terminology bulletin: 344). United Nations, New York, USA
[84] Wolfe supra note 83.

individuals who have disagreed with the medical decisions of their parents is well-documented. For example, "wrongful life" suits[85] or individuals who have disagreed with their parent's surgical decisions about sexual assignment or craniofacial disorders."[86] There are also groups of people who resist the idea of having their medical status defined as a "disability," and published cases of patients who are documented as stating they would not want to correct their medical condition if given the choice.[87]

The two principles, beneficence and non-maleficence, derives from the well-known Hippocratic Oath, "to help and do no harm.[88]" This age-old oath was established in the 4th century BCE by Hippocrates, a physician-philosopher. As with any new scientific discovery, the true long-term effects of CRISPR cannot be realistically gasped. Currently, the known possible negative effects of genetic engineering are off-target mutagenesis[89,90] and mosaicism[9192,93].

Applying a benefit-burden analysis, we must rely on alternative safer methods, such as, preimplantation genetic diagnosis, until we can reasonably and reliably predict the true effects of CRISPR.

Lastly justice, is a concept concerning fairness and equality. The more pragmatic concern involves a lack of accessibility, where "therapies," may be developed using this technology, but

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[85] J.R. Botkin, *The legal concept of wrongful life*, 1988, https://www.ncbi.nlm.nih.gov/pubmed/3339791
[86] K.E. Ormond et al. *Human Germline Genome Editing*., AM J HUM GENET. (2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5544380/#bib34.
[87] Hayden E. Check, *Should you edit your children's genes?* NATURE (2016)
[88] Epidemics, 1780
[89]S.W. Cho, *Analysis of off-target effects of CRISPR/Cas-derived RNA-guided endonucleases and nickases*, COLD SPRING HARBOR LABORATORY PRESS (2014)
[90] "However, off-target mutations observed at frequencies greater than the intended mutation, which may cause genomic instability and disrupt the functionality of otherwise normal genes, is still one major concern when applying CRISPR/Cas9 system to biomedical and clinical application." Xiao-Hui Zhang, *Off-target Effects in CRISPR/Cas9-mediated Genome Engineerin*g 4 CELL PRESS (2015)
[91] "Mosaicism occurs when two or more genetically distinct cell lines are derived from a single zygote." Kara A. Mensink, *Basic Concepts in Human Molecular Genetics*, ESSENTIAL CONCEPTS IN MOLECULAR PATHOLOGY (2010).
[92] Ormond supra note 87.
[93] Maryam Mehravar, M*osaicism in CRISPR/Cas9-mediated genome editing*, DEVELOPMENTAL BIOLOGY ( 2018).

may only be accessible to the wealthy would add to the already great wedge between socio-economic classes.

## Part II: The Current Laws Regulating Genomic Editing

Laws regulating genetic engineering vary by country, but because of the far-reaching consequences of this technology, many scientists have called for an international consensus on regulating ethically sound genetic engineering and banning unethical genetic engineering, or else face the many or all of the practical dangers and human rights violations I've illustrated above.

### A. The International Position on Gene-Editing

The United Nations (UN) is an international organization tasked with maintaining universal harmony as to peace, security, human rights and more[94]. Today, the UN has 193 member states[95] of the world's 206 countries. There are several specialized agencies under the UN, including the United Nations Educational, Scientific and Cultural Organization (UNESCO)[96], which seeks to promote international collaboration in education, science, and culture. After being called to prepare an international instrument for the protection of the human genome in 1993, UNESCO issued a declaration in 1997 entitled the "Universal Declaration on the Human Genome and Human Rights"[97] (the Declaration). Following release, a resolution entitled the "Implementation of the Universal Declaration on the Human Genome and Human Rights" was released by the General Conference outlining the methods of implementation of the Declaration[98]. Then in 1998, the Declaration was endorsed by the United Nations General

[94] http://www.un.org/en/sections/about-un/overview/index.html
[95] http://www.un.org/en/member-states/index.html
[96] https://en.unesco.org/about-us/introducing-unesco
[97] "Universal Declaration on the Human Genome and Human Rights (1997) and International Declaration on Human Genetic Data (2003)" full text: https://unesdoc.unesco.org/ark:/48223/pf0000253908
[98] "History of the Declaration" http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genome-and-human-rights/

Assembly[99]. The Declaration recognizes the importance of research on the human genome but emphasizes that that research must "fully respect human dignity, freedom and human rights…"[100] The Articles of particular relevance here include: 1, 2, 5, 10, 11, 12, 15 and 24. Article 1 recognizes that the human genome is symbolic of the heritage of all humankind, and as such, fundamental to the unity of the human family and their inherent dignity and diversity. Article 2 sets out a right to respect for human dignity. Article 5 goes into detail of the rights of the persons concerned, stating that prior to any research, treatment or diagnosis in relation to an individual's genomes a thorough risk-benefit assessment must be undertaken. It goes on to also state that prior, free and informed consent must be obtained, and when it cannot be obtained, authorization shall be obtained in accordance with the law and guided by the person's best interest. Article 15 calls States to provide a framework for the research on the human genome and to safeguard human rights, human dignity and to protect public health. Lastly, in Article 24, the Declaration suggests that germ-line gene editing could be contrary to human dignity. Outside of the important recognitions and recommendations set out by the Declaration, it serves only in the limited purpose of informing and guiding, and member states have no legally binding obligations.

In 2015, the International Bioethics Committee of UNESCO[101] or the IBC published a report, Report of the IBC on Updating its Reflection on the Human Genome and Human Rights. It stated that "[i]nterventions on the human genome should be admitted only for preventive, diagnostic or therapeutic reasons and without enacting modifications for descendants…The alternative would be to jeopardize the inherent and therefore equal dignity of all human beings

[99] Id History of the Declaration
[100] Id Universal Declaration
[101] https://en.unesco.org/news/unesco-panel-experts-calls-ban-editing-human-dna-avoid-unethical-tampering-hereditary-traits

and renew eugenics, disguised as the fulfilment of the wish for a better, improved life."[102] The same year IBC called on states and governments to agree on a moratorium on germline editing as the safety and efficacy of the procedures had not adequately proven as treatments.[103] It also recommended that states and governments to cooperate on establishing a unified global standard on the engineering of the human genome by building on the principles set out in the UN's Declaration.

**B. Europe**

In 1997, the Council of Europe[104,105] held an international conference named the Convention on Human Rights and Biomedicine, otherwise known as the Oviedo Convention[106]. The product was the first and only international text[107] that is a legally binding instrument on the protection of human rights in the biomedical field, namely designed to preserve human dignity, rights and freedoms. Under Chapter IV, Article 13, it explicitly prohibits germ-line editing. "An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and *only if its aim is not to introduce any modification in the genome of any descendants.*"[108] In other words, it only allows genetic engineering in somatic cells for rehabilitative purposes, namely preventative, diagnostic or therapeutic purposes. It also expressly prohibits making changes to the genetic make-up of a person's descendants,

[102] "Report of the IBC on Human Genome and Human Rights"; International Bioethics Committee; 2015 (http://unesdoc.unesco.org/images/0023/002332/233258E.pdf)
[103] page 3 of IBC report
[104] The Council of Europe is not the same as European Union because it cannot make binding laws, but it can enforce international agreements.
[105] https://www.coe.int/en/web/portal
[106] https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164
[107] "Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine," Council of Europe, European Treaty Series, No. 164, (https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98)
[108] Id to Convention text, [emphasis added].

disallowing genetic engineering of germ line cells for enhancement purposes. Those bound by this treaty are the 29 of the 47 member-states that signed and ratified it[109].

In 2000, the European Union created The Charter of Fundamental Rights of the European Union, or CFREU[110], which did not have legal effect until 2009 and it bound all members of the European Union. Under Article 3 in the CFREU, "Right to the integrity of the person," there is an explicit prohibition in the fields of medicine and biology from practicing eugenics, "in particular those aiming at the selection of person."[111]

Today, the several European state participants in the above legal documents remain the only countries, along with The United Kingdom, Canada, Mexico, Brazil and Australia to implement an express ban on human germline genetic engineering based on legislation[112]. Currently, countries like The People's Republic of China has a ban based only on guidelines that are less enforceable than laws[113]; and the United States of America has restrictions on germline genetic engineering but does not, to date, have a ban[114].

## C. People's Republic of China (China)

The November 2018 CRISPR baby scandal shocked the world and led many scientists and journalists to criticize not only China for its lack of regulation, but "the East." Meanwhile news outlets from China assert that He acted outside of the university, outside of the hospital and outside the law. So, which is it?

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[109] Notable states that did sign include France and Spain, and notable states that did not sign include Germany, the United Kingdom and the Russian Federation. Other states that signed but did not ratify: Italy, Sweden, Netherlands.
[110] "CHARTER OF FUNDAMENTAL RIGHTS
OF THE EUROPEAN UNION" http://www.europarl.europa.eu/charter/pdf/text_en.pdf
[111] Id
[112] See figure 3, Motoko Araki, *An international regulatory landscape regarding human germline gene modification*, REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY (2014).
[113] Id Motoko
[114] Id Motoko

China has regulatory instruments such as the Ministry of Health and the National Health and Family Planning Commission or the NHFPC that issues procedures for the management of human genetic resources and ethical principles for the governance of artificial reproductive technology. China also has the Chinese Food and Drug Administration or CFDA which issues good clinical practice standards and a regulation for the ethical review of biomedical research involving human subjects. The only relevant regulation China has is the 2003 Technical Norms of Human Assisted Reproduction, or the TNHAR, issued by the NHFPC. The TNHAR prohibits the manipulation of human genes in human gametes, zygotes or embryos for clinical or *reproductive* purposes, but did not place a ban on the use of embryo gene editing in basic and pre-clinical research. Additionally, these ethics guidelines do not specify punishments for such violations. The former vice president of the Ministry of Health's ethics committee, Qiu Renzong, has commented[115] that China has a lack of regulation, so Chinese scientists are only required to abide by the rules of their institutions, but even when they do violate those rules, there are no punishments. Another issue in China is the disjointed variation of the legal status of the human embryo between the different domains, for example, Chinese patent law affords embryos the legal status of a human being, while civil law characterizes them as ethical objects. Other identified ethical issues goes back to the heart of Chinese society and Chinese public opinion. It is believed that the one-child-policy in China has devalued unborn human life for over three decades in the eyes of the Chinese and has normalized pregnancy termination. And amongst scientists, there seems to be a utilitarian view on in vitro-fertilized embryos and aborted embryos. In fact, a study conducted by the Sun Yat-Sen University found that the Chinese public

[115] Catherine Lai, *Gene-edited babies and cloned monkeys: China tests bioethics*, SCIENCE X NETWORK (2018). https://phys.org/news/2018-11-gene-edited-babies-cloned-monkeys-china.html#jCp.

widely supports therapeutic use of gene editing in adults and children, however it does not directly address germline editing.[116]

So how exactly did He Jiankui pull off this scandalous event? According to news reports, He skirted all the rules by not obtaining approval from his university for the clinical trial; by failing to inform the staff researchers working on the trial of the true nature of the project and by retrospectively registering the clinical trial after the work was complete with the Chinese authorities[117]. He did however receive approval from the Medical Ethics Committee of the First Affiliated Hospital, Sun Yat-Sen University in Guangzhou, China[118].

The University made a statement,[119] announcing that He acted outside of the school by failing to report the research to his department and the school and that the Academic Committee of the Department of Biology of the school found that his acts were deemed to be serious violations of academic ethics and academic norms. They finally asserted that the school has strict requirements as to scientific research which complies with international academic ethics and academic norms and that they have launched an investigation and plan to publish relevant information. Additionally, officials from China's national health commission have also stated that they would investigate He's unlawful behavior. Further, per the South China Morning Post, over 120 Chinese scientists have signed an open letter to He, condemning him for his work.[120]

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[116] Liang Chen, *Chinese Public Attitudes on Gene Editing*, GLOBAL TIMES, http://www.globaltimes.cn/pdf/ChinesePublicAttitudesOnGeneEditing2018.11.12.pdf.
[117] Lily Kuo, *Work on gene-edited babies blatant violation of the law, says China*, THE GUARDIAN, https://www.theguardian.com/science/2018/nov/29/work-on-gene-edited-babies-blatant-violation-of-the-law-says-china.
[118] Krishan supra note 81.
[119] http://www.sustc.edu.cn/news_events_/5524?from=timeline&isappinstalled=0.
[120] Alice Shen, *Chinese scientists condemn 'crazy' and 'unethical' gene-editing experiment*, SOUTH CHINA MORNING POST (2018), https://www.scmp.com/news/china/society/article/2175105/chinese-scientists-condemn-crazy-and-unethical-gene-editing.

Astonishingly, an article[121] that He co-authored has also surfaced, where he proposes and outlines ethical principles as to the clinical applications of germline gene-editing.

Lastly, it has also been speculated whether He's experiment was well-intentioned in response to China's history with HIV[122] or ill-intentioned, given that he has started several companies and is the CEO of his own DNA sequencing company, Direct Genomics.[123] As of the date of this article, China has not yet acted, in fact, it is not known exactly where He is, but it has been reported that He was suspended without pay,[124] and other news reports have reported that He has been detained[125]. Whether or not China's deficient regulation or He's malfeasance is to blame, Lulu and Nana's human rights have been violated. Some of He's work has been reviewed by independent scientists who have raised concerns about He having altered both the CCR5 gene in one twin, but only having altered one copy in the other[126]. Another concern is that although He contends he personally procured informed consent from all the parents that participated in the trial[127], this information remains unverified as the identities of all the couples have remained anonymous.

## D. The United States of America

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[121] He Jiankui et al., *Draft Ethical Principles for Therapeutic Assisted Reproductive Technologies*, THE CRISPR JOURNAL (2018), https://www.liebertpub.com/doi/10.1089/crispr.2018.0051.
[122]Kathleen McLaughlin, *China's history with AIDS explains a puzzling aspect of the 'CRISPR babies' story*, STAT NEWS, https://www.statnews.com/2018/12/14/china-aids-history-crispr-babies/.
[123] Andrew Joseph, *An outsider claimed to make genome-editing history — and the world snapped to attention*, STAT NEWS, https://www.statnews.com/2018/11/26/he-jiankui-gene-edited-babies-china/.
[124] Christian Edwards, *Chinese researcher behind genetically edited babies is now under investigation and suspended without pay*, THE BUSINESS INSIDER, (2018), https://www.businessinsider.com/dna-modified-babies-researcher-under-investigation-suspended-2018-11.
[125] Xeni Jardin, *He Jiankui, scientist who gene-edited 'Crispr babies', detained in China*, BOING BOING; (2018), https://boingboing.net/2018/12/03/china-baby-edit-scientist.html.
[126] Id Joseph
[127] Sharon Begley, *Amid uproar, Chinese scientist defends creating gene-edited babies*, STAT NEWS, https://www.statnews.com/2018/11/28/chinese-scientist-defends-creating-gene-edited-babies/

It is important to note that as of the date of this paper, December 2018, the United States has not yet banned gene-editing, but there are two legislative initiatives and an executive branch response that does address and limit uses of genetic engineering technologies.

### 1. Legislative Branch and Funding

The Dickey-Wicker amendment of 1996[128] and the Omnibus Spending Bill of 2015 prohibit the remittance of federal funding for germ-line gene editing, but is silent on somatic gene editing.

In 1996, the Dickey Wicker Amendment passed through Congress which bans the Department of Health and Human Services (HHS) from making federal funding available for:

> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and 42 U.S.C. 289g(b).For purposes of this section, the phrase "human embryo or embryos" shall include any organism, not protected as a human subject under 45 CFR 46 as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes.

In 2015, the Subcommittee on Research and Technology of the U.S. House of Representatives Committee on Science, Space and Technology held a hearing[129] and issued a charter[130] named The Science and Ethics of Genetically Engineered Human DNA. This hearing was followed by Congress passing a $1.1 trillion Omnibus Spending Bill that increased the budget of the National Institute of Health (NIH) by $2 billion. Congress also placed new

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[128] THE BALANCED BUDGET DOWNPAYMENT ACT, I, 1996 Enacted H.R. 2880, 104 Enacted H.R. 2880, 110 Stat. 26, 104 P.L. 99, 1996 Enacted H.R. 2880, 104 Enacted H.R. 2880

[129] https://science.house.gov/legislation/hearings/subcommittee-research-and-technology-hearing-science-and-ethics-genetically

[130] https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-114-SY15-20150616-SD001.pdf

restrictions on the use of the federal funding specifically so that no funds would be made available for embryonic gene-editing. While restrictions on federal funding provide for a deterrence mechanism, the potential of growth and economics within the science community are commonly measured by private investments[131]. Companies include Editas Medicine, a firm known to have obtained licenses for gene editing patent rights and CRISPR, raised $94.4 million in its 2016 initial public offering.[132] CRISPR Therapeutics AG, a firm founded by a co-inventor of CRISPR, raised a total of $96 million in 2016.[133] Caribou Biosciences, Inc., another firm founded by another co-inventor of CRISPR, raised a total of $30 million in 2016.[134]

### 2. Executive Branch Regulation

Francis S. Collins, the director of the NIH, an operating division under the Department of Health and Human Services, has made two statements of relevance. In 2015[135], following the passing of the funding guidelines from Congress, he expressly stated the NIH would not fund germ-line gene-editing, he cited safety and ethical issues, such as lack of consent of future generations, and a current lack of compelling medical applications that would justify the use on embryos. Then in 2018,[136] following Dr. He Jiankui's presentation at the 2018 International Summit on Human Genome Editing, Collins called his work "deeply disturbing." Collins reiterated that the NIH does not support germ-line gene-editing and he goes even further to call

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[131] Marcy E. Gallo et al., *Advanced Gene Editing: CRISPR-Cas9*, CONGRESSIONAL RESEARCH SERVICE (2017)
[132] Id. Gallo
[133] Id. Gallo
[134] Id. Gallo
[135] *Statement on NIH funding of research using gene-editing technologies in human embryos*, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos
[136] *Statement on Claim of First Gene-Edited Babies by Chinese Researcher*, https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-claim-first-gene-edited-babies-chinese-researcher

for the development of binding international consensus on setting limits for genome editing research.

In 2017, the National Academies of Sciences, Engineering, and Medicine or the Academies, created a congressional charter, released a statement saying that germline gene-editing could one day be permitted under stringent oversight, and recommending that only clinical trials involving somatic editing of diseases and disabilities should be allowed at this time in scientific research.[137]

The Federal Food and Drug Administration (FDA), a federal governing body under the executive branch is charged with promoting and protecting public health and enforcing laws in accordance with those duties. The FDA is empowered to regulate gene-editing technologies pursuant to two acts: "drugs[138]" and "devices[139]" under The Federal Food, Drug and Cosmetic Act of 1939 (FDCA)[140] and "biological products" under The Public Health Service Act of 1944 (PHSA)[141]. In an article posted on the FDA website, "Therapeutic Cloning and Genome Modification,[142]" it states that the FDA "has regulatory authority over genetically manipulated cells and/or their derivatives." Lastly, similar to China, before any clinical use of gene-edited embryos can be implanted for pregnancy, permission must be granted from the FDA, whereas in China, the Ministry of Health grants permissions.[143]

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[137] Alta Charo et al., *With Stringent Oversight, Heritable Germline Editing Clinical Trials Could One Day Be Permitted for Serious Conditions; Non-Heritable Clinical Trials Should Be Limited to Treating or Preventing Disease or Disability at This Time*, NATIONAL ACADEMIES OF SCIENCES, ENGINEERING AND MEDICINE (2017), http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24623.

[138] Defined under the FDCA partially as, "articles intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

[139] Defined under the FDCA partially as, "an instrument, apparatus, implement..or other similar or related article…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals…"

[140] The Federal Food, Drug and Cosmetic Act of 1939 (FDCA); U.S.C. 301 et seq.

[141] The Public Health Service Act of 1944 (PHSA); U.S.C. 201 et seq.

[142] https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm2007205.htm

[143] dam P. Cribbs et al., *Science and Bioethics of CRISPR-Cas9 Gene Editing: An Analysis Towards Separating Facts and Fiction*, YALE JOURNAL OF BIOLOGY AND MEDICINE (2017).

### c. What does the Public Think?

In a 2016 survey[144] titled, "A Global Social Media Survey of Attitudes to Human Genome Editing," over 12,000 people were surveyed on their opinions of gene-editing, which contrary to popular belief, is more popular than not in respondents recruited through social media who had a median age of 24, with people mostly from the United States of America, the United Kingdom, Japan or China. Most notably, 59.0% of respondents supported gene-editing in children and adults to cure life-threatening diseases and 59.4% of respondents supported gene-editing to cure debilitating diseases. Further, 43.3% of respondents disagreed with the use of gene editing technology for non-health related purposes. Per the survey, respondents viewed both somatic and germ-line editing applications as comparable. In another surprising survey[145] conducted in 2018, found that most Americans, 72%, think it is appropriate to use technology to germline edit for therapeutic purposes.

## F. Conclusion

There is a need for global consensus on genetic engineering as the human rights of two newly born twins have been violated. While there are countries that have banned germline editing like Canada[146], there are many countries with ambiguous rules[147] and even still, countries with troubling stances on the topic[148]. Guidelines grounded in ethics are required to avoid

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[144] Tristan McCaughey et al., *A Global Social Media Survey of Attitudes to Human Genome Editing* 18 FORUM 569 (2016)

[145] Cary Funk et al., *Public Views of Gene Editing for Babies Depend on How It Would Be Used*, PEW RESEARCH CENTER (2018)

[146] In 2004, Canada passed the Assisted Human Reproduction Act which placed a criminal ban on gene-editing and also placed sanctions which range from a fine of up to $500,000 to imprisonment of up to 10 years.

[147] Motoko Araki, *International regulatory landscape and integration of corrective genome editing into in vitro fertilization*, REPRODUCTIVE BIOLOGY AND ENDOCRINOLOGY (BioMed Central Ltd, 2014)

[148] The Japanese Environmental Ministry, a governmental committee, has recommended deregulation of some forms of gene-editing. Xavier Symons, *Japanese committee recommends no regulation for some gene editing*, BIOEDGE (2018), https://www.bioedge.org/bioethics/japanese-committee-recommends-no-regulation-for-some-forms-of-gene-editing/1278)

additional human rights violations, because even if we all collectively banned germline cell editing, human rights could still be violated with somatic cell editing. I have summarized a potentially problematic application of somatic cell editing below.

**Part III: Potentially Problematic Applications**

If the United States were to adopt the generally accepted regulatory framework as their peer countries, there are still numerous potential applications that are ethically problematic and morally questionable, I will discuss one: criminal intervention.

**a) Criminal intervention**

From the crime scene, to the courtroom, the criminal justice has long been aided by science and mathematics. These fields are respected as their findings are most reliable and when used properly, irrefutably accurate. Before DNA testing and forensics were fully developed into the tool as it is used today in the criminal justice system, in the 1970s we had already started to begin to collect and store DNA swabs and samples from crime scenes before we even had the ability to test that information accurately, knowing we would one day have the necessary scientific resources to do so[149]. Today, science's role is an important aspect of criminal convictions, science floods the discovery proceedings with every kind of niche expert witness such as forensic engineers, toxicologists and blood spatter analysts. The United States of America has long been criticized for its unsustainable and inefficient criminal justice system, and efforts are increasingly made to correct the flawed system, such as bail reform[150] and juvenile offender reform,[151] from both sides of the political spectrum. The current president of the US, Donald Trump has gone so far as to say on CNN, "We [] have to come up with punishment that is far

[149] J. Hirby, *History of DNA Testing in Criminal Cases*, THE LAW DICTIONARY, https://thelawdictionary.org/article/history-of-dna-testing-in-criminal-cases/.
[150] Jon Schuppe, *Post Bail*, NBC NEWS (2017), https://www.nbcnews.com/specials/bail-reform.
[151] https://www.congress.gov/bill/115th-congress/house-bill/1809/text

quicker and far greater than the punishment these animals are getting right now. [] We need quick justice and we need strong justice. Much quicker and much stronger than we have right now. Because what we have right now is a joke and is a laughing stock.[152]"

We have also long sought to deter delinquency and to make sense of why crime exists, but what if we had the power to stop it? I have no doubt that if we were to think of the most heinous and worst offenders of human society, most people would want something to be done about it, if we could. Could we do something about serial killers and pedophiles? Maybe science will take us there one day, but today, this proposition is entirely theoretical.

In an article from Oxford, "Prior to the discovery of CRISPR-Cas9, the emerging debate about the legal implications of the relationship between MAOA and violent crime focused on whether such information should mitigate offender culpability, or whether it should increase length of detention as it suggests that an offender is a poor candidate for rehabilitation. CRISPR-Cas9 could shift this debate, as direct intervention becomes possible: the technology could provide a tool to help prevent violent crime, or deal with repeat offenders.[153]"

According to a dissertation by Kevin Beaver, currently a professor of criminology at Florida State University entitled, "THE INTERSECTION OF GENES, THE ENVIRONMENT, AND CRIME AND DELINQUENCY: A LONGITUDINAL STUDY OF OFFENDING[154]," there are five different genes that with certain environmental interactions give insight behind criminal or delinquent behavior, those are DAT1, DRD2, DRD4, 5HTT and MAOA. He concludes by stating that biosocial research is important and is needed to explain how crime comes to be, "as

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[152] Dan Merica, *Trump labels US justice system 'laughingstock'*, CNN, (2017), https://www.cnn.com/2017/11/01/politics/trump-justice-laughing-stock/index.html

[153] Sarah Polcz, *CRISPR-Cas9 and the non-germline non-controversy* 3 JOURNAL OF LAW AND THE BIOSCIENCES 413, https://academic.oup.com/jlb/article/3/2/413/1751234.

[154] Kevin Beaver, *The Intersection of Genes, the Environment, and Crime and Delinquency: A Longitudinal Study of Offending*, (2010), https://www.ncjrs.gov/pdffiles1/nij/grants/231609.pdf.

the 21st century marches on, biosocial criminology will hold the key to uncovering the dynamic processes that unfold and contribute to the development of antisocial behaviors. Until a biosocial approach to the study of crime is accepted, traditional theories of crime will remain underdeveloped, incomplete, and impoverished. With the recent mapping of the human genome and with almost daily discoveries about the function of certain genes, the time is ripe to embrace biosocial explanations to the study of crime and delinquency."

I now turn to MAOA or as it is colloquially known as the "human warrior gene." MAOA is an enzyme, scientifically known as monoamine oxidase A. A mutation of MAOA can cause a rare genetic disorder leading to an MAOA deficiency which results in excess monoamine transmitters in the brain like serotonin and dopamine. This deficiency causes "excessive impulsive behavior including hypersexuality, sleep disorder and extreme mood swings as well as a tendency to violence, which is known as Brunner syndrome."[155] This deficiency was first reported by a Dutch geneticist Han Gerrit Brunner after observing about five generations of a family in the Netherlands. He found that all the men seemed to have a proclivity for violence, "[o]ne had tried to rape his sister; another had tried to run his boss down with a car; a third had forced his sisters to undress at knife point. Furthermore, the violent streak had a long history. In 1962 the woman's granduncle had prepared a family tree that identified nine other males with the same disorder, tracing it as far back as 1870." Brunner and his colleagues found that this was defect was inherited via the X chromosome, which crippled the MAOA enzyme which helps regulate aggressive behavior.[156] In an experiment conducted in 1995, mice that lacked MAOA were found to be highly aggressive, but when MAOA was reintroduced, they returned to their

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[155] Philip Hunter, *The psycho gene*, EMBO REPORTS. 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2933872/

[156]Sarah Richardson, *Violence in the Blood*, DISCOVER MAGAZINE (1993), http://discovermagazine.com/1993/oct/aviolenceinthebl293/?src=longreads

normal behavior.[157] Gene editing could disproportionately impact minority groups who have increasing chances of carrying the MAOA deficiency. For example, another study found that the MAOA deficiency seemed to be more prevalent among the Māori of New Zealand than among the non-native New Zealand Caucasians[158][159].

Use of behavior genetic evidence has already been used in criminal proceedings, and there is at least one case in the United States in which expert testimony on MAOA was introduced and lead to the reduced sentence of the defendant.[160] Bradley Waldroup was charged with first degree murder and attempted first degree murder after a domestic dispute that carried the death penalty[161]. The jury returned a verdict of voluntary manslaughter and attempted second-degree murderer. Waldroup was sentenced to the maximum term, 32 years in prison.

As Kevin Beaver points out, this research is far more complex than the standard nature versus nurture conversation typically had. The genes alone do not just act alone, there is an environment-factor as well. Jim Fallon, a professor of psychiatry at the University of California, is a person who has a lot of murderers in his family tree and carries the genes that would tend to say that he would be more inclined to commit violent acts. But Professor Fallon has never displayed them[162].

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[157] O. Cases, *Aggressive behavior and altered amounts of brain serotonin and norepinephrine in mice lacking MAOA.*, PUBMED, https://www.ncbi.nlm.nih.gov/pubmed/7792602

[158]Rod Lea, *Monoamine Oxidase, Addiction, and the "Warrior" Gene Hypothesis*, THE NEW ZEALAND MEDICAL, https://www.researchgate.net/publication/6466626_Monoamine_Oxidase_Addiction_and_the_Warrior_Gene_Hypothesis.

[159] Compare to, "There is no direct evidence to support the claim that the MAO-A gene confers 'warrior' qualities on Māori males, either modern or ancestral." Vicky Cameron, *Risk-taking: behind the warrior gene story*, 120 THE NEW ZEALAND MEDICAL 1250, https://www.researchgate.net/publication/6466625_Risk-taking_Behind_the_warrior_gene_story.

[160] Sally McSwiggan, *The Forensic Use of Behavior Genetics in Criminal Proceedings: Case of the LAOA-L* Genotype, 50 INTERNATIONAL JOURNAL OF LAW AND PSYCHIATRY 17-23, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5250535/

[161] Colin Barras, *The controversial debut of genes in criminal cases*, BBC, http://www.bbc.com/future/story/20180530-the-controversial-debut-of-genes-in-criminal-cases

[162] *Are murderers born or made?*, BBC NEWS, https://www.bbc.com/news/magazine-31714853

Even if germline cell genetic engineering was banned, somatic cell genetic engineering would have numerous potentially problematic and ethically unsound applications, aside from criminal intervention, like military enhancement,[163] just to name a few.

**Conclusion**

Lulu and Nana are the first genetically modified human on earth. Lulu and Nana did not consent to this treatment. In fact, their entire genetic bloodline who will carry this edited gene in perpetuity has not consented. A grave dishonor has been perpetrated on the personal autonomy and human dignity of the twins and their future progeny. While scientists have predicted potentially harmful effects,[164] they cannot know the unknown. He violated the human rights of not only the twins but of humankind. He opened a door that we can never close. Until a global consensus is formed, the potential for human right violations through germline and somatic genetic engineering remains open.

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[163] M. Greene, *Ethical Issues of Using CRISPR Technologies for Research on Military Enhancement*, J. BIOETH. INQ. (2018).

[164] Ed Yong, *The CRISPR Baby Scandal Gets Worse by the Day*, SCIENCE, https://www.theatlantic.com/science/archive/2018/12/15-worrying-things-about-crispr-babies-scandal/577234/.